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(54) Title: CONTROLLED RELEASE DOSAGE FORMS USING ACRYLIC POLYMER, AND PROCESS FOR MAKING THE SAME

(57) Abstract: Process for dry mixing a controlled release oral dosage form are provided. The dosage form is produced by mixing, tableting, and curing dosage forms. The cured dosage forms exhibit controlled release properties superior to those of uncured tablets.

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A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KRAJACIC, A. AND TUCKER, I. G.: "Curing dose dumping from a matrix tablet" PROCEEDINGS- 28TH INTERNATIONAL SYMPOSIUM ON CONTROLLED RELEASE OF BIOACTIVE MATERIALS AND 4TH CONSUMER & DIVERSIFIED PRODUCTS CONFERENCE, vol. 1, - June 2001 (2001-06) pages 816-817, XP009005881 the whole document	1,4,5,7, 12-14
Y	----- -/--	10-15

☒ Further documents are listed in the continuation of box C.

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	LEHMANN ET AL: "Formulation of controlled release tablets with acrylic resins" ACTA PHARMACEUTICA FENNICA, SUOMEN FARMASEUTTINEN YHDITYS, HELSINKI, FI, vol. 93, no. 2, 1984, pages 55-74, XP002100607 ISSN: 0356-3456 page 64, line 20 -page 69, line 7 ----	10-15
A	US 6 159 501 A (SKINHOJ ANNETTE) 12 December 2000 (2000-12-12) example 10 ----	12
A	LIPPOLD, B.C. AND MONELLS PAGES, R: "Control and stability of drug release from diffusion pellets coated with the aqueous quaternary polymethacrylate dispersion Eudragit (R) RS 30 D" PHARMAZIE, vol. 56, no. 6, - June 2001 (2001-06) pages 477-483, XP001135276 the whole document ----	10-15
A	MAEJIMA, TORU ET AL: "Influence of film additives on stabilizing drug release rates from pellets coated with acrylic polymers" PHARMACEUTICAL DEVELOPMENT AND TECHNOLOGY (2001), 6(2), 211-221 , XP002231366 the whole document ----	10-15
A	WO 01 32148 A (EURO CELTIQUE SA ;HUANG HUA PIN (US); MASSELINK JOHN (US); OSHLACK) 10 May 2001 (2001-05-10) page 23, line 6 -page 30, line 12; examples 1-4 ----	10-15
A	US 6 103 261 A (CHASIN MARK ET AL) 15 August 2000 (2000-08-15) examples ----	10-15
A	US 5 639 476 A (OSHLACK BENJAMIN ET AL) 17 June 1997 (1997-06-17) column 14, line 44 -column 15, line 67; examples -----	10-15

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6159501	A	12-12-2000	AU 2021997 A	22-09-1997
			CN 1217655 A	26-05-1999
			WO 9732573 A1	12-09-1997
			EA 1773 B1	27-08-2001
			EP 0888111 A1	07-01-1999
			HU 9901779 A2	28-10-1999
			NO 984038 A	04-11-1998
			PL 328687 A1	15-02-1999
WO 0132148	A	10-05-2001	AU 1446501 A	14-05-2001
			EP 1227798 A1	07-08-2002
			NO 20022014 A	20-06-2002
			WO 0132148 A1	10-05-2001
US 6103261	A	15-08-2000	US 5958459 A	28-09-1999
			US 6316031 B1	13-11-2001
			US 5681585 A	28-10-1997
			US 6143322 A	07-11-2000
			US 6129933 A	10-10-2000
			AT 172376 T	15-11-1998
			AU 722358 B2	27-07-2000
			AU 5299598 A	26-03-1998
			AU 716793 B2	09-03-2000
			AU 5299998 A	26-03-1998
			AU 6605894 A	12-01-1995
			AU 6610594 A	12-01-1995
			CA 2126611 A1	02-01-1995
			CA 2127166 A1	02-01-1995
			CN 1102323 A	10-05-1995
			CN 1103289 A	07-06-1995
			CZ 9401550 A3	18-01-1995
			CZ 9401601 A3	15-03-1995
			DE 69414046 D1	26-11-1998
			DE 69414046 T2	22-04-1999
			DK 636370 T3	28-06-1999
			EG 20650 A	31-10-1999
			EP 1243269 A2	25-09-2002
			EP 0631781 A1	04-01-1995
			EP 0636370 A1	01-02-1995
			ES 2124372 T3	01-02-1999
			FI 943141 A	02-01-1995
			FI 943168 A	02-01-1995
			HU 75164 A2	28-04-1997
			HU 70938 A2	28-11-1995
			IL 109944 A	06-12-1998
			IL 110014 A	30-11-1999
			JP 7145056 A	06-06-1995
			JP 7149648 A	13-06-1995
			KR 140492 B1	01-06-1998
			NO 942470 A	02-01-1995
			NO 942477 A	02-01-1995
			NZ 260825 A	26-01-1996
			NZ 260883 A	24-06-1997
			NZ 280243 A	24-06-1997
			PL 304060 A1	09-01-1995
			PL 304062 A1	09-01-1995
			SG 50706 A1	20-07-1998
			SK 76394 A3	09-08-1995

BEST AVAILABLE COPY

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6103261	A		SK 78694 A3	08-02-1995
			TW 450814 B	21-08-2001
			US 6294195 B1	25-09-2001
			US 5968551 A	19-10-1999
			US 2002081333 A1	27-06-2002
<hr/>				
US 5639476	A	17-06-1997	US 5580578 A	03-12-1996
			US 5286493 A	15-02-1994
			US 5958459 A	28-09-1999
			US 6143353 A	07-11-2000
			AU 686168 B2	05-02-1998
			AU 6868994 A	09-02-1995
			CA 2128591 A1	28-01-1995
			EP 0636366 A2	01-02-1995
			US 6294195 B1	25-09-2001
			US 5968551 A	19-10-1999
			AT 184786 T	15-10-1999
			AU 660512 B2	29-06-1995
			AU 2967992 A	29-07-1993
			BR 9204577 A	03-08-1993
			CA 2074309 A1	28-07-1993
			DE 69230028 D1	28-10-1999
			DE 69230028 T2	13-04-2000
			DK 553392 T3	06-03-2000
			EG 20307 A	31-10-1998
			EP 0553392 A1	04-08-1993
			ES 2141713 T3	01-04-2000
			GR 3032106 T3	31-03-2000
			HK 1005687 A1	20-04-2000
			HU 66961 A2	30-01-1995
			IL 102851 A	10-06-1997
			JP 5201856 A	10-08-1993
			MX 9205823 A1	01-07-1993
			NO 924597 A	28-07-1993
			NZ 245298 A	26-07-1995
			PL 297534 A1	18-10-1993
			RU 2127587 C1	20-03-1999
			SG 44698 A1	19-12-1997
			US 2002081333 A1	27-06-2002
			ZA 9206587 A	02-03-1993

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